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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/743,023 03/07/01 HEMMENDORFF

B 10806-155

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HM22/0619

EXAMINER

GHASHGHAEI, F

ART UNIT	PAPER NUMBER
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1656

DATE MAILED:

06/19/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/743,023

Applicant(s)

HEMMENDORFF ET AL.

Examiner

Fariba Ghashghaee

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-8,11-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-8,11-19 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-8, and 11-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Christensen, T.(WO 96/02570A1).

Christensen discloses a method for the production of recombinant peptides by reducing the amount of trisulfide bridges in rhGH by treating the rhGH with a sulfite of alkali or alkaline earth metals at PH 3-11, preferably 7(See claims 2 and 7).

Christensen explains that the addition of sulfite salts converts trisulfite bridges into disulfide bridges. Christensen has performed his experiment in which recombinantly produced GH is treated with a salt at PH 7 and reported the reduction of content of trisulfide bridges (See Abstract, page 3, line 28-page 5, line 17, and claims).

Christensen also disclosed the use of growth hormone and wherein the growth hormone is a human growth hormone (See claims 1 and 10).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5-8, and 11-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sorensen et al. (WO 94/24157), and further in view of Breton et al. ("Detection of traces of a trisulphide derivatives in the preparation of a recombinant truncated interleukin-6 mutein", J. Chromatography, Vol. 709, 1995, pg. 135-146).

Sorensen teaches a method for the production of recombinant peptides wherein the peptide is a human growth hormone(See Abstract and page 14, lines 15-20), and explains that the experiments were carried out at different PH values ranging 4.3-7.5 (See page 16, lines 25-26). Sorensen also teaches the effect of sulfur atoms on the production of rhGH (See page 7, lines 20-25).

Sorensen does not teach specifically the reduction of trisulfide and its effect on production of recombinant peptide.

Breton et al. teaches a method for reducing the trisulfide to disulfide and its effect on the production of recombinant protein (See page 145).

It would have been prime facie obvious to one of ordinary skill in the art at the time the invention was made to combine the Sorensen's method for production of recombinant peptide with the reduction method of Breton to make the claimed inventions.

The person of ordinary skill in the art would have been motivated to make these inventions and would have been expected reasonable level of success because Breton teaches the effect of reduction of trisulfide on the production of recombinant peptide(See page 145).

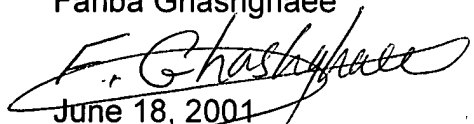
Advisory Information

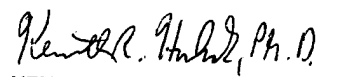
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fariba Ghashghaee whose telephone number is (703)305-3586. The examiner can normally be reached on 8:30 A.M.-4:30 P.M. on Mon.-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703)308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703)305-3014 for regular communications and (703)305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

Fariba Ghashghaee


June 18, 2001


KENNETH R. HORLICK
PRIMARY EXAMINER
GROUP 1600 6/18/01